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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,250	07/12/2006	Fouad El-Baroudi	0617-1004	4947

466 7590 03/07/2011  
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EXAMINER
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BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

NOTIFICATION DATE	DELIVERY MODE
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03/07/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,250	<b>Applicant(s)</b> EL-BAROUDI, FOUAD	
	<b>Examiner</b> Michael Borin	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06/08/2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8 and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                     |                                                                   |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                         | 6) <input type="checkbox"/> Other: _____                          |

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#### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/08/2010 has been entered.

#### **Status of Claims**

Claims 1-6,8,9 are pending.

#### ***Claim Rejections - 35 USC § 112, second paragraph.***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6,8,9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claim 1 is amended to contain three steps directed to producing altered digital model of the bone joints, each of which seeming to be independent from others :

- adjusting geometry of the model using data specific to a patient
- adjusting digital model by a set of interaction parameters derived from applying constraints on the interaction of rigid body pairs and determining mobility and stiffness, and
- making digital model by correcting positions of 3D curve of rigid bodies in space

Since each of these steps seems to be independent , it is not clear i) whether there is any interrelationship between the steps, and ii) which step(s) result(s) in the claimed objective of biomechanical simulation. For example, the first and third steps recited above do not require applying constraints on the interaction of rigid body pairs, and thus will result in a model different from the model obtained by the second step recited above. Therefore, the metes and bounds of the claims are not clear, and one of ordinary skills in the art would not be reasonably appraised of the scope of the invention and of the subject matter that will be protected by the patent grant.

B. Claim 1: The step of defining of interaction parameters: Adjustment of digital model in this step requires particular interaction parameters; however, the sub-steps addressing defining the parameters do not result in defining particular parameters. Rather, the sub-step of determining mobility and global stiffness

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results in "approximating" parameters. It is not clear therefore, which parameters are being used to adjust the digital model. Further, it is not clear, in the sub-step of determining mobility and global stiffness, how the determined mobility and global stiffness produces interaction parameters defining geometry of the model.

***Claim Rejections - 35 USC § 112, first paragraph.***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6,8,9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Applicant points at paragraphs [0024]-[0026] and asserts that no New Matter has been added. However, the specification does not appear to provide an adequate written description of the following limitation of claim 1:

..determining a mobility or global stiffness resulting from "the applying ...constraint on the interaction of ...rigid bodies". Specification does not disclose determining a mobility or global stiffness resulting from the

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applying a constraint. Rather, specification teaches that applying a constraint leads to recalculating personalized model (paragraph [0024]), not to determining a mobility or global stiffness as now claimed. Same paragraph mentions mobility or stiffness that are "different from that corresponding to the behavioral law " and not that are defined from and determined by applying a constraint. Further, paragraph [0025] teaches defining mobility or global stiffness parameters resulting from insertion, not from applying a constraint. Specification does not teach that an "insertion element" and a "constraint" are equivalents.

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations

***Claim Rejections - 35 USC § 103.***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness

rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6,8,9 are rejected under 35 U.S.C.103(a) as obvious over Aouni-Ateshian (US 6,161,080)

The instant method is directed to method of biomechanical simulation of bone joints in a patient comprising

- A. Recording in a reference position of a three-dimensional digital model represented by rigid bodies connected by joints
- B. Adjusting geometry of the model using data specific to a patient
- C. Adjusting the model by a set of interaction parameters for each joint.

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Interaction parameters are defined by acquiring and documenting positions of rigid bodies and determining mobility or global stiffness resulting from applying a constraint on interaction of rigid bodies to approximate the parameters.

D. Making the model by correcting 3D digital reconstruction and determining the distribution of points in the 3D curve associated with rigid bodies, positioned in the Stokes coordinate system and their associated tangent

As addressed in the rejection under USC, 112, second paragraph above, the metes and bounds of the claimed subject matter are not clear as steps B-D address what seems to be alternative steps of achieving the objective of simulating a body joint. To this end, the following rejection addresses elements of the invention as instantly claimed.

6,161,080 teaches method of generating a three dimensional representation of anatomical joints comprising the steps by acquiring three-dimensional anatomically representative data of two or more



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movable bodies of a selected joint, selecting one or more link types responsive to said representative data

of the bodies, and selecting link characteristics responsive to each selected link type. See claim 2, for

example:

2. A method of generating a three dimensional representation of more than one anatomical joint on an output device, wherein said representation comprises two or more movable bodies and one or more links associated with the selected number of joints, comprising the steps of:  
acquiring anatomically representative data of two or more movable bodies of a selected number of joints;  
selecting one or more link types responsive to said representative data of the bodies for each of the selected number of joints;  
selecting link characteristics responsive to each selected link type;  
generating an equilibrium condition responsive to interaction between the bodies and the links;  
and  
displaying a three dimensional representation of said anatomical joints on the output device responsive to the data generated from the equilibrium condition for the selected number of joints.

The model includes both geometric (see col.3, lines 40-56, col. 4, col. 32, lines 34-50) and stiffness parameters (e.g., col. 3, lines 16-40). Further, the model combines multiple bodies and reflects their relative positions (see, e.g., col. 2, bottom, col.34, lines 11+). Further, the model addresses multiple constraints - see claim 6 and col. 29, section 5.2.10. The data generated from the equilibrium condition

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responsive to interaction between the bodies and links predict the kinematic orientation, the kinematic position, the contact force, and the contact area of the movable bodies and links (claim 3)

With regard to the steps directed to "adjusting using interaction parameters", the referenced model addresses multiple constraints – see claim 6 and col. 29, section 5.2.10. Further, '080 patent teaches:

Once the patient joint geometry is obtained, a patient specific model can be constructed and analyzed to suggest a best physical therapy program or a surgical procedure. One of the advantages of the multibody model is its rapid convergence by using an efficient analytical Jacobian formulation and contact calculation. It also provides sophisticated interactive graphics to view the three-dimensional model, and menu-driven windows to easily modify model parameters. Through all these features, the model allows a user to interactively modify different geometric and structural parameters, and observe the effects of these parameters almost immediately. The user can explore various parameters efficiently and quantify their mechanical effects on the joint.

With regard to step D. of claim 1, first, '080 patent teaches that the geometry of large number of points on the joint surfaces are approximated by polynomials in space (col. 3, lines 40-56). Further, the patent teaches reproduction of the measured positions – see claim 13, last step.

With regard to claims 2,4,6,9 the model includes both geometric (see col.3, lines 40-56, col. 4, col. 32, lines 34-50) and stiffness parameters (e.g., col. 3, lines 16-40). Geometric entities included

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bone geometry and articular surface geometry, as well as insertion locations for ligaments and tendons (col.

32 , lines 34+). Further, with regard to claim 9, the model addresses insertion elements; see sections

5.2.4, 5.2.5, 6.2.

Further, with regard to claim 5, "personalization" step involves acquiring and analyzing image information ;

see col. 32-33, for example.

The reference does not teach some method steps of the instant method which seem to be purely technical details, such as building a digital table, positioning the model in Stokes coordinate system. Such differences would appear minor in nature. It would be conventional and within the skill of the art to select and/or determine such conditions for data analysis as selection of such condition is result-oriented and is conventional and within the skill of the art and would be obvious to, and within the skill of artisan in the art to which this invention pertains.

Further, it appears that certain permutation of embodiments (or "models") addressed in '080 patent are described as different models (same as instant claims seem to combine alternative steps). See col. 3-

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4, for example. If so, applying the KSR standard of obviousness (*KSR Int'l* 7, 127 S. Ct. at 1740) the combination of different embodiments would be obvious to one skilled in the art as it represents a combination of known elements which yield the predictable result of comprehensive and adjustable simulation of bone joints.

### ***Prior art made of record***

In addition to previously cited, the following prior art is made of record and considered pertinent to applicant's disclosure:

Gignac et al. (Gignac et al. European Spine Journal, Volume 9, Number 3, 185-190, 2000) teaches optimization method for 3D bracing correction of scoliosis using a finite element model of the spine in order to find optimal correction patterns.

### ***Conclusion.***

No claims are allowed